

Generic Name: Topotecan

Therapeutic Class or Brand Name: Hycamtin[®]

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 2155008010

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 1/17/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

- I. Documented diagnosis of relapsed small cell lung cancer.
- II. Patient has relapsed after a complete or partial response at least 45 days from the end of first-line chemotherapy.
- III. Minimum age requirement: 18 years old.
- IV. The prescribing physician is an oncologist.

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- The recommended dose of Hycamtin[®] capsules is 2.3 mg/m²/day once daily for 5 consecutive days repeated every 21 days. The calculated oral daily dose should be rounded to the nearest 0.25 mg, and the minimum number of 1 mg and 0.25 mg capsules should be prescribed. The same number of capsules should be prescribed for each of the 5 dosing days. The quantity is limited to a maximum of a 30-day supply per fill.

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/hycamtin_caps.pdf.
2. NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf
3. Medi-Span.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
1/17/2020	<ol style="list-style-type: none"> 1. Added "NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf" under References 2. Deleted "http://www.fchp.org/~media/Files/FCHP/Imported/Hycamtin_oral_topotecan.pdf.ashx" and "https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/hycamtin-commercial-direct" under References.
12/4/2018	<ol style="list-style-type: none"> 1. Policy reviewed: no changes made.
12/29/2017	<ol style="list-style-type: none"> 1. Policy reviewed: no changes made.
10/7/2016	<ol style="list-style-type: none"> 1. Updated "http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/hycamtin.pdf" to "https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/hycamtin-commercial-direct" and "http://us.gsk.com/products/assets/us_hycamtin_capsules.pdf" to "https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/hycamtin_caps.pdf" under References. 2. Removed "http://www.connecticare.com/provider/PDFs/Pharmacy/Hycamtin.pdf" from References (link no longer valid).
5/8/2015	<ol style="list-style-type: none"> 1. Removed "Severe bone marrow depression" from Exclusion Criteria.
1/21/2014	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added GPI Code. 3. Changed Prior Authorization Criteria from: "Documented diagnosis of relapsed small cell lung cancer; Patient has relapsed after a complete or partial response at least 45 days from the end of first-line chemotherapy with platinum agent and etoposide; Patient is unable to use IV formulation of Topotecan; Minimum age requirement: 18 years old; Provider is an oncologist" to: "Documented diagnosis of relapsed small cell lung cancer; Patient has relapsed after a complete or partial response at least 45 days from the end of

	<p>first-line chemotherapy; Minimum age requirement: 18 years old; The prescribing physician is an oncologist".</p> <p>4. Added "Severe bone marrow depression" to Exclusion Criteria.</p> <p>5. Changed Quantity/Days Supply Restrictions from "Quantity Limits: 15 Hycamtin® 0.25mg capsules and 25 Hycamtin® 1mg capsules per 21 days" to "The recommended dose of Hycamtin® capsules is 2.3 mg/m²/day once daily for 5 consecutive days repeated every 21 days. The calculated oral daily dose should be rounded to the nearest 0.25 mg, and the minimum number of 1 mg and 0.25 mg capsules should be prescribed. The same number of capsules should be prescribed for each of the 5 dosing days. The quantity is limited to a maximum of a 30 day supply per fill".</p> <p>6. Updated references to include Medi-Span.</p>
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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.